of "Genetic Control T-Cell Proliferative Baxevanis al., et Responses to Poly (Glu<sup>40</sup>Ala<sup>60</sup>) and Poly (Glu<sup>51</sup>Lys<sup>34</sup>Tyr<sup>15</sup>): Subregion-00 Inhibition of Responses the Specific with 1980, 11: 617-628 Antibodies", <u>Immunogenetics</u>, Mustohor DATE CONSIDERED EXAMINER 04/05/05

123(1): 272-278 (Abstract)

## U.S. Department of Commerce Patent and Trademark Office

Atty. Docket No. 60726-A

Serial No. 09/885,227

OCT 2 2 2002 8

CHADEMARY

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Applicants
Moses Ro

Moses Rodriguez and Daren Ure

Filing Date
June 20, 2001

Group Art Unit 1614 1646

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Maurer et al., "Interpretations of Immune Responses of Mice to Poly(Glu60Lys40), its Modified Derivatives, and the Terpolymers Poly (Glu55Lys37Leu8) and Poly (Glu56Lys37Ser7)", Clin. Immunol. Immunopathol., 1980, 15(3): 344-356 (Abstract)

Herzenberg et al., "Lack of Immune Response Gene Control for Induction of Epitope-specific Suppression by TGAL Antigen", <u>Nature</u>, 1982, 295: 329-331 (Abstract)

Babu et al., "Reevaluation of Response Patterns of Nonresponder Mice to GlPhe Polymers", <u>Immunogen.</u>, 1983, 18(1): 97-100 (Abstract)

Babu et al., "Ir Gene Control of T and B Cell Responses to Determinants in (Glu Lys Ala) Terpolymer", <u>J. Immunogenet</u>., 1984, 11(3-4): 251-254

Falo et al., "Analysis of Antigen Presentation by Metabolically Inactive Accessory Cells and Their Isolated Membranes", <u>Proc. Natl. Acad. Sci.</u> <u>USA</u>, 1985, 82(19): 6647-6651 (Abstract)

Trannoy et al., "Epitope-specific Regulation of the T Cell Repertoire: Carrier Recognition in Association with I-E or I-A Does Not Influence the Restriction of Hapten-Specific T Cells", <u>Eur. J. Immunol</u>., 1985, 15(12): 1215-1221 (Abstract)

Lai et al., "Complementation of Class II a Alleles in the Immune Response to (Glulystyr) Polymers", <u>Exp. Clin. Immunogenet</u>., 1986, 3(1): 38-48 (Abstract)

Lai et al., "Monoclonal T Cell Responses to Two Epitopes on a Single Immunogen Controlled by Two Distinct Genes", <u>J. Immunol</u>., 1986, 136(10): 3799-3804 (Abstract)

De Kruyff et al., "Analysis of T Cell Responses to Poly-L (GluLys) at the Clonal Level. I. Presence of Responsive Clones in Nonresponder Mice", <u>Eur. J. Immunol</u>., 1987, 17 (8): 1115-1120 (Abstract)

Matsunaga et al., "Complementation of Class II A Alleles in the Immune Response to (Glu-Lys-Tyr) Polymers", <u>Yokohama Med. Bull</u>., 1988, 39(1-2): 9-19 (Abstract)

Zisman et al., "Direct Binding of a Synthetic Multichain Polypeptide to Class II Major Histocompatibility Complex Molecules on Antigenpresenting Cells and Stimulation of a Specific T-cell Line Require Processing of the Polypeptide", <u>Proc. Natl. Acad. Sci. USA</u>, 1991, 88(21): 9732-9742 (Abstract)

Deeb et al., "Comparision of Freund's and Ribi Adjuvants for Inducing Antibodies to the Synthetic Antigen (TG)-AL in Rabbits", <u>J. Immunol.</u> <u>Methods</u>, 1992, 152(1): 105-113 (Abstract)

Kropshofer et al., "Self-Peptides from Four HLA-DR Alleles Share Hydrophobic Anchor Residues Near the  $\mathrm{NH_2}\text{-}\mathrm{Terminal}$  Including Proline as a Stop Signal for Trimming", <u>J. Immunol</u>., 1993, 151: 4732-4742

EXAMINER Olleyslaw

DATE CONSIDERED

04/09/03

Serial No. U.S. Department of Commerce Form PTO-1449 Atty. Docket No. 09/885,227 Patent and Trademark Office 60726-A Applicants CORMATION DISCLOSURE CITATION Moses Rodriguez and Daren Ure (Use several sheets if necessary) OCT 2 2 2002 & Group Art Unit Filing Date 1614 /646 OC June 20, 2001 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) CRADEMAR! Zisman et al., "Dichotomy Between the T and the B Cell Epitopes of the Synthetic Polypeptide (T,G)-A-L", Eur. J. Immunol., 1994, 24(10): 2497-2505 (Abstract) "A Unique Population of Circulating Rodriquez, Asakura and Autoantibodies Promotes Central Nervous System Remyelination", Multiple <u>Sclerosis</u>, 1998, <u>4</u>: 217-221 Asakura et al., "Targeting of IgMx Antibodies to Oligodendrocytes Promotes CNS Remyelination", <u>J. Neurosci</u>., 1998, <u>18</u>(19): 7700-7708 Li et al., "Glatiramer Acetate Blocks the Activation of THP-1 Cells by Interferon-y", <u>Eur. J. Pharmacol</u>., 1998, 342: 303-310 Pavelko et al., "Acceleration in the Rate of CNS Remyelination in Lysolecithin-Induced Demyelination", J. Neurosci., 1998, 18(7): 2498-2505 Rodriguez, Neurological Therapeutics, 1998, 15(3): 245-250 Cohen, "Fundamental Immunology", Systemic Autoimmunity, 4th Ed., 1999, 04 1083 Fridkis-Hareli et al., "Binding of Random Copolymers of Three Amino Acids to Class II MHC Molecules", <u>Intl. Immunol</u>., 1999, <u>11</u>(5): 635-641 McGavern et al., "Do Antibodies Stimulate Myelin Repair in Multiple Sclerosis", <u>The Neuroscientist</u>, 1999, <u>5</u>(1): 19-28 Bieber et al., "Antibody-Mediated Remyelination: Relevance to Multiple Sclerosis", <u>Multiple Sclerosis</u>, 2000, <u>6</u>: S1-S5 Henry, Celia M., "Special Delivery", Chem, and Eng. News, Sept. 18, 2000, 49-54 Monoclonal Antibodies Reactive et al., "Human Warrington Oligodendrocytes Promote Remyelination in a Model of Multiple Sclerosis", <u>Neurobiology</u>, 2000, <u>97</u>(12): 6820-6825 Bieber et al., "Humoral Autoimmunity as a Mediator of CNS Repair", Trends in Neurosci., 2001, 24(11): S39-S44 Warrington et al., "Immunoglobulin-Mediated CNS Repair", J. Allergy <u>Immunol</u>., 2001, S121-S125 🧸 ZUO2 --- CENTER 1600/2900 04/03/03 Eller show EXAMINER DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through

citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**U.S.** Department of Commerce Serial No. . Docket No. Form PTO-1449 09/885,227 60726-A Patent and Trademark Office Applicants OIPEINFORMATION DISCLOSURE CITATION Moses Rodriguez and Daren Ure Group Art Unit (Use several sheets if necessary) Filing Date OCT 2 2 2002 8 1614 /646 June 20, 2001 **U.S. PATENT DOCUMENTS** E TRADEAL Subclass Filing Date Date Name Class **Document Number** if Appropriate Initial 2/17/98 Acton III, et al. US Konfino et al. 9/1/98 US 1/12/99 Aharoni et al. US J 11/9/99 Konfino et al. US Ш US 9 9/28/99 Hupe et al. OC П Konfino et al. 9 4/11/00 US 6 0 US 6 0 4/25/00 Konfino et al. m 6 2 4/10/01 Arnon et al. US Konfino et al. 1/29/02 US FOREIGN PATENT DOCUMENTS **Translation** Subclass Country Class **Document Number** Date Yes No US  $WO \cup 0$ 4/13/00 5/18/00 IUS. |WO|0US Ю 2/3/00 11/15/01 US  $\mathbf{WO}[0]$ OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Webb, et al., "In Vivo and in Vitro Immunological Cross-reactions between Basic Encephalitogen and Synthetic Basic Polypeptides Capable of Suppressing Experimental Allergic Encephalomyelitis", <u>Eur. J. Immunol.</u>, 1973, <u>3</u>, 279-286 et al., "Dose-response Studies on Experimental Teitelbaum, Allergic Encephalomyelitis Suppression by COP-1", Israel J. Med. <u>Sci.</u>, 1974, <u>10</u>(9), 1172-1173 al., "Suppression of Experimental Allergia Teitelbaum, et Encephalomyelitis in Rhesus Monkeys by a Synthetic Basid Copolymer", Clin. Immunol. Immunopath., 1974, 3, 256-262 06 of Experimental Allergid "Suppression al., Webb, et Synthetic by a Encephalomyelitis Rhesus Monkeys Basid in Copolymer", <u>Isr. J. Med. Sci.</u>, 1975, <u>11</u>, 1388 (Abstract) Webb, et al., "Molecular Requirements Involved in Suppression of EAE by Synthetic Basic Copolymers of Amino Acids", Immunochem., 1976, <u>13</u>, 333-337 Abramsky, et al., "Effect of a Synthetic Polypeptide (COP-1) on Patients with Multiple Sclerosis and with Acute Disseminated Encephalomyelitis", <u>J. Neurol. Sci.</u>, 1977, <u>31</u>, 433-438 DATE CONSIDERED 04/09/03 Elleuf Amy **EXAMINER** \*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line

through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce Patent and Trademark Office OCT 2 2 200ENSEORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ay. Docket No. 60726-A

Applicants

Moses Rodriguez and Daren Ure

Filing Date June 20, 2001

U.S.	<b>PATENT</b>	<b>DOCUMENTS</b>

Examiner Document Number Initial				r	Date Name		Class	Subclass	Filing Date if Appropriate					
/	US	3	8	4	9	5	5	0	11/19/74	Teitelbaum et al.				
	US	4	3	3	9	4	3	1	7/13/82	Gaffar			古	_ ====
oc	US	5	2	0	4	0	9	9	4/20/93	Barbier et al.			F 0	8 1
/	US	5	5	9	1	6	2	9	1/7/97	Rodriguez et al.			E	2 m
/	US	5	6	2	7	2	0	6	5/6/97	Hupe et al.			罗	~ 7
1	US	5	6	6	8	1	1	7	9/16/97	Shapiro et al.			1600/29	002 <b>m</b>
FOREIGN PATENT DOCUMENTS											-7	<u>%</u>	U	

			Document Number						er	Date	Country	Class	Subclass	Translation	
														Yes	No
		wo	8	8	1	0	1	2	0	12/29/88	US				1
		wo	9	5	3	1	9	9	0	11/30/95	US				
	oc	wo	9	5	3	3	4	7	5	12/14/95	Europe				
,		wo	9	8	3	0	2_	2	7	7/16/98	US				
7		wo	()	0	0	5	2	5	0	2/3/00	US				
		wo	0	0	1	8	7	9	4	4/6/00	US	_/			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	Teitelbaum, et al., "Suppression of Experimental Allergic
	Encephalomyelitis by a Synthetic Polypeptide", Israel J. Med.
4	<u>Sci.</u> , 1971, <u>7</u> , 630-631 (Abstract)
$/ \mid$	Teitelbaum, et al., "Suppression of Experimental Allergio
	Encephalomyelitis by a Synthetic Polypeptide", Eur. J. Immunol.,

1971, <u>1</u>, 242-248 of Experimental Allergia "Suppression al., et

Encephalomyelitis by a Synthetic Copolymer Immunological Cross Reactive with Basic Encephalitogen", <u>Israel J. Med. Sci.</u>, 1972, <u>8</u>, 1759-1760

Teitelbaum, et al., "Protection Against Experimental Allergid Encephalomyelitis", Nature, 1972, 240, 564-566

Webb, et al., "Further Studies on the Suppression of Experimental Allergic Encephalomyelitis by Synthetic Copolymer", Israel J. Med. <u>Sci.</u>, 1972, <u>8</u>, 656-657

et al., "Suppression of Experimental Allergid Teitelbaum, Encephalomyelitis with Basic Polymers", Eur. J. Immunol., 1973, <u>3</u>, 273-279

EXAMINER

TRADEN

Munfold

DATE CONSIDERED

04/05/03

Sheet <u>3</u> of <u>12</u> Serial No. Atty. Docket No. U.S. Department of Commerce Form PTO-1449 09/885,227 60726-A Patent and Trademark Office Applicants Moses Rodriguez and Daren Ure INFORMATION DISCLOSURE CITATION OCT 2 2 2002 (Use several sheets if necessary) Group Art Unit Filing Date June 20, 2001 U.S. PATENT DOCUMENTS Subclass Filing Date Class Date **Document Number** Name Examiner i**t A**ppropriate Initial US 20 01 00 55 56 8 A1 12/27/01 Gilbert et al. П lus 10913 7/22/99 Strominger et al. R 06 0 5 US 094 9/24/99 Gad et al. US 10917 1/23/01 6 Aharoni et al. US 098 3/23/01 Gad et al. FOREIGN PATENT DOCUMENTS **Document Number** Subclass Translation Country Class Date Yes No | wolo | 11 8/23/01 lUS 12/13/01 WO|0OC 8 WO012/27/01 US 8/22/90 EP 0 3 Europe 11/29/95 Europe OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) al., "Suppression of Experimental Allergid et Teitelbaum, Encephalomyelitis in Baboons by Cop 1", <u>Israel J. Med. Sci.</u>, 1977, 13, 1038 (Abstract) Arnon, et al., "Suppression of EAE in Baboons by a Synthetic Polymer of Amino Acids", Neurol., 1978, 28, 336 (Abstract) Sela, et al., "Experimental Allergic Encephalomyelitis" Menarini Series on Immunopathology, vol. 1, First Symposium of Organ Specific Autoimmunity", Cremona, Italy, June, (Miescher P.A. ed., Schwabe Co., Basel, 1978), 9-21 Alvord, et al., "Myelin Basic Protein Treatment of Experimental 60 Allergic Encephalomyelitis in Monkeys", Ann. Neurol., 1979, 6, 469-473 Keith, et al., "The Effect of COP 1, a Synthetic Polypeptide, on Chronic Relapsing Experimental Allergic Encephalomyelitis in Guinea Pigs" <u>J. Neurol. Sci.</u>, 1979, <u>42</u>, 267-274 Lando, et al., "Effect of Cyclophosphamide on Suppressor Cell Activity in Mice Unresponsive to EAE", J. Immunol., 1979, 123, 2156-2160 (Abstract) Lando, et al., "Experimental Allergic Encephalomyelitis in Mice Suppression and Prevention with COP-1", Israel J. Med. Sci., 1979,

EXAMINER Illufam

DATE CONSIDERED

15, 868-869 (Abstract)

04/05/03

<u>Sheet 4</u> of <u>12</u> Atty. Docket No. Serial No. U.S. Department of Commerce Form PTO-1449 09/885,227 60726-A Patent and Trademark Office Applicants INFORMATION DISCLOSURE CITATION Vioses Rodriguez and Daren Ure OCT 2 2 2002 % (Use several sheets if necessary) Ptiling Date Group Art Unit 00 1614 /646 June 20, 2001 TRADEMAR OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Teitelbaum, et al., "Blocking of Sensitization to Encephalitogenic Basic Protein in Vitro by Synthetic Basic Copolymer (COP 1)" in Cell Biology and Immunology of Leukocyte Function (Academic Press, New York, 1979) 681-685 Teitelbaum, "Suppression of Experimental Allergic Encephalomyelitis with a Synthetic Copolymer - Relevance to Multiple Sclerosis", in Humoral Immunity in Neurological Diseases (Karcher D., Lowenthal A. & Strosberg A.D., eds., Plenum Publishing Corp., 1979) 609-613 "Desensitization Experimental al., of Encephalomyelitis with Synthetic Peptide Analogues" in The Suppression of Experimental Allergic Encephalomyelitis and Multiple Sclerosis (Academic Press, New York, 1980) 105-107 Arnon, "A Synthetic Copolymer of Amino Acids in a Clinical Trial for MS Therapy" in Progress in Multiple Sclerosis Research (Bauer, Ritter, eds., Springer Verlag New York, 1980) 416-418 Bornstein, et al., "Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results", Ann. Neurol., 1980, 8, 117 (Abstract) C Bornstein, et al., "Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results", Trans. Am. Neurol. Assoc., 1980, 105, 348-350 McDermott, et al., "Antigen-induced Suppression of Experimental Allergid Neuritis in the Guinea Pig", J. Neurol. Sci., 1980, 46, 137-143 "Experimental Allergic Encephalomyelitis - Susceptibility and Suppression", Immunological Rev., 1981, 55, 5-30 al., "Multiple Sclerosis: Trial of a Synthetic Bornstein, et Polypeptide", <u>Ann. Neurol.</u>, 1982, <u>11</u>, 317-319 Brosnan, et al., "The Response of Normal Human Lymphocytes to Copolymer 1", <u>J. Neuropath. Exp. Neurol.</u>, 1983, <u>42</u>, 356 (Abstract) Lisak, et al., "Effect of Treatment with Copolymer 1 (Cop-1) on the in in Vitro Manifestations of Experimental Allergid Encephalomyelitis (EAE)", J. Neurol. Sci., 1983, 62, 281-293 Trials of Copolymer 1 in Multiple et al., "Clinical Sclerosis", <u>Ann. N.Y. Acad. Sci. (USA)</u>, 1984, 366-372 Synthetic Polypeptide "Clinical Trials of a Bornstein, et al., (Copolymer 1) for the Treatment of Multiple Sclerosis" in Gonsett et al., Immunclogical and Clinical Aspects of Multiple Sclerosis (MTP Press, The Hague, 1984) 144-150 EXAMINER CHULLISTAN 84/05/03 DATE CONSIDERED \*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to

applicant.

TECH CENTER 1600/2900 Sheet <u>5</u> of <u>12</u> Serial No. Form PTO-1449 **U.S. Department of Commerce** Atty. Docket No. 09/885,227 Patent and Trademark Office 60726-A Applicants INFORMATION DISCLOSURE CITATION Moses Rodriguez and Daren Ure (Use several sheets if necessary) Group Art Unit 1614 0c Filing Date OCT 2 2 2002 & June 20, 2001 TRADEMARY OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Brosnan, et al., "Copolymer 1: Effect on Normal Human Lymphocytes", Ann. N.Y. Acad. Sci. (USA), 1984, 436, 498-499 Bornstein, et al., "Multiple Sclerosis: Clinical Trials of a Synthetic Polypeptide, Copolymer 1", <u>Neurol.</u>, 1985, <u>35</u> (Suppl. 1), 103 (Abstract) Brosnan, et al., "Immunogenic Potentials of Copolymer 1 in Normal Human Lymphocytes", <u>Neurol.</u>, 1985, <u>35</u>, 1754-1759 Burns, et al., "Human Cellular Immune Response in Vitro to Copolymer 1 and Myelin Basic Protein (MBP)", <u>Neurol.</u>, 1985, <u>35</u> (Suppl. 1), 170 (Abstract) Teitelbaum, et al., "Monoclonal Antibodies to Myelin Basic Protein Cross React with Synthetic EAE-suppressive Copolymer, COP 1" in Proc. 7th Eur. Immunol. Mtg., Jerusalem, September 8-13, 1985 (Abstract) Thompson, "MCQ Tutor: Medical Immunology Multiple Choice Questions", Immunol. Today, 1985, <u>6</u>(4), 141 Burns, et al., "Human Cellular Immune Response to Copolymer 1 and Myelin Basic Protein", <u>Neurol.</u>, 1986, <u>36</u>, 92-94 Bornstein, "Cop 1 May be Beneficial for Patients with Exacerbatingremitting Form of Multiple Sclerosis", Adv. Ther. (USA), 1987, 4, 206 (Abstract) Bornstein, et al., "A Pilot Trial of Cop 1 in Exacerbating-remitting Multiple Sclerosis", New Eng. J. Med., 1987, 317(7), 408-414 "Copolymer-I Therapy for Multiple Sclerosis", Clin. Rolak, Neuropharmacology, 1987, <u>10</u>(5), 389-396 Winer, "COP 1 Therapy for Multiple Sclerosis", New Eng. J. Med., 1987, <u>317</u>(7), 442-444 Arnon, et al., "Suppression of Demyelinating Diseases by Synthetid Copolymers", in <u>A Multidisciplinary Approach to Myelin Disease</u> (G. Serlupi Crescenzi, ed., Plenum Publishing Corp., 1988) 243-250 Baumhefner, et al., "Copolymer 1 as Therapy for Multiple Sclerosis: The Cons", <u>Neurol.</u>, 1988, <u>38</u>(Suppl. 2), 69-71 al., Experience "Clinical with COP-1 Multiple Bornstein, et Sclerosis", <u>Neurol.</u>, 1988, <u>38</u>(Suppl. 2), 66-69 Teitelbaum, et al., "Specific Inhibition of the T-cell Response to Myelin Basic Protein by the Synthetic Copolymer Cop 1" , Proc. Natl. Acad. Sci, USA, 1988, 85, 9724-9728 EXAMINER MULLY SWY 04/09/03 DATE CONSIDERED

Serial No. **U.S.** Department of Commerce Form PTO-1449 Attv. Docket No. Patent and Trademark PECEIVED 09/885,227 60726-A **Applicants** (Use several sheets if necessary) Moses Rodriguez and Daren Ure P PERFORMATION DISCLOSURE CITATION 2 4 2002 Group Art Unit 6 Filing Date 1614 1646 TECH CENTER 1600/250me 20, 2001 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Ferrara, et al., "Graft-Versus-Host Disease", New Eng. J. Med., 1991, <u>324</u>, 667-674 Meiner, "COP-1 Multicenter Clinical Trial in Exacerbating-remitting Multiple-Sclerosis: One Year Follow-up", J. Neurol., 1991(Suppl. 1) (Abstract) Rothbard, et al., "Interactions Between Immunogenic Peptides and MHC Proteins", <u>Ann. Rev. Immunol.</u>, 1991, <u>9</u>, 527-565 Salvetti, et al., "Myelin Basic Protein T Cell Epitopes in Patients with Multiple Sclerosis", Department of Neurological Sciences, University of Rome, La Sapienza 1991, 72 (Abstract) Teitelbaum et al., "Cross-reactions and Specificities of Monoclonal Antibodies Against Myelin Basic Protein and Against the Synthetic Copolymer 1", <u>Proc. Natl. Acad. Sci. (USA)</u>, 1991, <u>88</u>, 9528-9532 Van den Bogaerde, et al., "Induction of Long-Term Survival of Hamster Heart Xenografts in Rats", Transplantation, 1991, 52, 15-20 Bornstein, et al., "Treatment of Multiple Sclerosis with Copolymer 1" in Treatment of Multiple Scleorsis: Trial Design, Results and Future Perspectives (Rudick R.A. & Goodkin D.E., eds., Springer Verlag, London, 1992) 173-198 Johnson, "Clinical Studies in Copolymer 1 Therapy for Exacerbatingremitting Multiple Sclerosis", in Congress for Advances in the Understanding and Treatment of Multiple Sclerosis, Boston (USA), Oct. 28-29, 1992 Milo, et al., "Inhibition of Myelin Basic Protein-specific Human T-cell Lines by COP-1", <u>Israel J. Med. Sci.</u>, 1992, <u>28</u>, 486 (Abstract) Racke, et al., "Copolymer-1-induced Inhibition of Antigen-specific T Activation: Interference with Antigen Presentation", Cell Neuroimmunol., 1992, <u>37</u>, 75-84 Teitelbaum, et al., "Synthetic Copolymer 1 Inhibits Human T-cell Lines Specific for Myelin Basic Protein", Proc. Natl. Acad. Sci. (USA), 1992, <u>89</u>, 137-141 "Natural History and Treatment of Multiple et al., Weinshenker Sclerosis", Current Opinion in Neurol. and Neurosurgery, 1992, 5, 203-"T Suppressor Hybridomas and Interleukin-2-Dependent Aharoni et al., Lines Induced by Copolymer 1 or by Spinal Cord Homogenate Down-Regulate Experimental Allergic Encephalomyelitis", Eur. J. Immunol., 1993, 23, 17-25

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

DATE CONSIDERED

EXAMINER Clumber

04/05/03

TECH CENTER 1600/2900

Sheet <u>6</u> of <u>12</u>

Serial No. **U.S. Department of Commerce** Form PTO-1449 Atty. Docket No. 09/885,227 60726-A Patent and Trademark Office Applicants ANNORMATION DISCLOSURE CITATION Moses Rodriguez and Daren Ure Group Art Unit OCT 2 2 2002 (C) (Use several sheets if necessary) Filing Date 1614 /646 June 20, 2001 TRADEMARY OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Arnon, et al., "Suppression of Experimental Allergic Encephalomyelitis by Cop-1 - Relevance to Multiple Sclerosis", <u>Israel J. Med. Sci.</u>, 1989, 25, 686-689 Bornstein, et al., "Pilot Trial of COP-1 in Chronic Progressive Multiple Sclerosis: Preliminary Report", from The International Multiple Sclerosis Conference: An Update on Multiple Sclerosis, Roma (Italy), September 15-17, 1988, in <u>Elsevier Science Publisher</u>, 1989, 225-232 Teitelbaum, et al., "Clinical Trial of Copolymer 1 in Multiple Sclerosis" <u>J. Israel Med. Assoc.</u>, 1989, <u>CXVI</u>(9), 453-456 Bornstein, et al., "Clinical Trials of Cop 1 in Multiple Sclerosis" in Handbook of Multiple Sclerosis (S.D. Cook Marcel Rekker, ed., 1990) 469-Carter, et al., "Newer Drug Therapies for Multiple Sclerosis", Drug Therapy, 1990, 31-32, 37-39, 42-43 Grgacic, et al., "Cell-mediated Immune Response to Copolymer 1 in Multiple Sclerosis Measured by the Macrophage Procoagulant Activity Assay", <u>Int. Immunol.</u>, 1990, <u>2</u>(8), 713-718 Kay, et al., "The Mechanism of Action of FK 506", Transplantation Proceedings, 1990, 22(1, Suppl. 1), 96-99 Lee, et al., "Peptide and Protein Drug Delivery" in Advances in Parenteral Sciences (Vincent H.L. Lee, ed., Marcel Dekker, Inc., 1990) 691-695 Myers, et al., "The Peculiar Difficulties of Therapeutic Trials for Multiple Sclerosis", <u>Neurologic Clinics</u>, 1990, <u>8</u>(1), 119-141 Sela, et al., "Suppressive Activity of COP-1 in EAE and its Relevance to Multiple Sclerosis", <u>Bull. Inst. Pasteur</u>, 1990, <u>88</u>, 303-314 Starzl, Transplantation Proceedings, 1990, 22 (1, Suppl. 1), 5 Wender, "Copolymer 1 (COP-1) in the Treatment of Multiple Sclerosis (letter)" <u>Neur. Neurochir. Pol.</u>, 1990, <u>24</u>, 113 Bornstein, et al., "A Placebo-controlled, Double-blind, Randomized Twocenter, Pilot Trial of Cop 1 in Chronic Progressive Multiple Sclerosis", Neurol., 1991, 41, 533-539 Burns, et al., "Failure of Copolymer 1 to Inhibit the Human T-cell 1991, <u>41</u>, 1317-1319 Response to Myelin Basic Protein", Neurol., Clinical Trial Protocol No. 9001, Teva Pharmaceutical Industries, Ltd., first patient enrolled October 23, 1991 EXAMINER Cluy stuy DATE CONSIDERED 04/05/03 \*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line

through citation if not in conformance and not considered. Include copy of this form with next communication to

applicant.

## U.S. Department of Commerce Patent and Trademark Office

(Use several sheets if necessary)

O P PRORMATION DISCLOSURE CITATION

Atty, Docket No. 60726-A

Serial No. 09/885,227

Applicants

Moses Rodriguez and Daren Ure

Filing Date June 20, 2001 Group Art Unit 1614 /646 0C

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

et al., "Immunomodulation of Experimental Allergid Arnon, Encephalomyelitis", <u>Israel J. Med. Sci.</u>, 1993, <u>29</u>, 175-181

Arnon, et al., "On the Existence of Suppressor Cells", Int. Arch. Allergy Immunol., 1993, <u>100</u>, 2-7

Clinical Trial Protocol No. 9002, Lemmon Co. and Teva Pharmaceutical Industries, Ltd., first patient enrolled June 17, 1993

Francis, "The Current Therapy of Multiple Sclerosis", J. Clin. Pharmacy <u>and Therapeutics</u>, 1993, <u>18</u>, 77-84

al., "Graft-versus-Host Disease in Bone Keleman, et Transplantation: Experimental, Laboratory, and Clinical Contributions of the Last Few Years", <u>Int. Arch. Allergy Immunol</u>., 1993, <u>102</u>, 309-320

Gurevich, "Study of the MHC-competition Between BP and Cop 1 Using Human Cytotoxic T-cell Clones", <u>Israel J. Med. Sci.</u>, 1993 (Abstract)

Meiner, et al., "The Israeli COP-1 Multicenter Clinical Trial in Exacerbating-remitting Multiple Sclerosis - Two-year Follow-up", in 9th Congress of the European Committee for Treatment and Research in Multiple Sclerosis, Florence (Italy), October-November, 1993, (Abstract)

Milo, et al., "Copolymer-1 (COP-1) Regulates Class II MHC Expression and Cytokine Synthesis in the THP-1 Monocyte-Macrophage Cell Line" in The IBC Conference on Multiple Sclerosis, San Diego (USA), December 10, 1993 (Abstract)

Sela, "Polymeric Drugs as Immunomodulatory Vaccines Against Multiple Sclerosis", Makromol. Chem. Macromol. Symp., 1993, 70/71, 147-155

Arnon, et al., "Immunospecific Drug Design - Prospects for Treatment of Autoimmune Disease", Therapeutic Immunol., 1994, 1, 65-70

Bansil, et al., "Multiple Sclerosis: Pathogenesis and Treatment", <u>Seminars in Neurol.</u>, June 1994, <u>14</u>(2), 146-153

The COP-1 Multicenter Clinical and Research Group Study, "COP-1 Multicenter Trial in Relapsing Remitting Multiple Sclerosis: 3 Year Follow Up", Abstracts of Symposia and Free Communication, Barcelona (Spain), June 25-29, 1994, <u>241</u> (Suppl. 1), 6

"Options for Multiple Sclerosis Therapy", J.A.M.A. Medical News Cotton, & Perspectives, 1994, <u>272</u>(18), 1393

Dorling, et al., "Prospects for Xenografting", Curr. Opinions Immunol. 1994, <u>6</u>, 765-769

EXAMINER Melley Chan

DATE CONSIDERED

04/09/03

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with Dext communication to applicant.

11 2 4 2002

U.S. Department of Commerce Patent and Trademark Office

Atty. Docket No. 60726-A

Serial No. 09/885,227

Applicants
INFORMATION DISCLOSURE CITATION

Moses Rodriguez and Daren Ure

OCT 2 2 2002 (Use several sheets if necessary)

Filing Date
June 20, 2001

Group Art Unit

TRADEMARK OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Fridkis-Hareli, et al., "Copolymer 1 Displaces MBP, PLP and MOG, but Can Not be Displaced by these Antigens from the MHC Class II Binding Site", Department of Chemical Immunology, The Weizmann Institute of Science, 1994

Fridkis-Hareli, et al., "Direct Binding of Myelin Basic Protein and Synthetic Copolymer 1 to Class II Major Histocompatibility Complex Molecules on Living Antigen-Presenting Cells - Specificity and Promiscuity", <u>Proc. Natl. Acad. Sci. USA</u>, 1994, <u>91</u>, 4872-4876

Fridkis-Hareli, et al., "Specific and Promiscuous Binding of Synthetic Copolymer 1 to Class II Major Histocompatibility Complex Molecules on Living Antigen Presenting Cells", <u>Israeli Biochem. Soc.</u>, 1994, 21-22 (Abstract)

Fridkis-Hareli, et al., "Synthetic Copolymer 1 Inhibits the Binding of MBP, PLP and MOG Peptides to Class II Major Histocompatibility Complex Molecules on Antigen Presenting Cells" in <u>Neurochem Mtg., August 14-19,</u> 1994

Fridkis-Hareli, et al., "Synthetic Copolymer 1 Inhibits the Binding of MBP, PLP and MOG Peptides to Class II Major Histocompatibility Complex Molecules on Antigen- Presenting Cells", <u>J. Neurochem.</u>, 1994, <u>53</u>(Suppl. I), 561

Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein Do Not Undergo Processing Prior to the Binding to Class II Major Histocompatibility Complex Molecules on Antigen Presenting Cells", Israeli Immunol. Soc., May 3-4, 1994 (Abstract)

Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein do not Require Processing Prior to Binding to Class II Major Histocompatibility Complex Molecules on Living Antigen Presenting Cells", <u>Department of Chemical Immunology, The Weizmann Institute of</u> Science, Rehovot, Israel, 1994

Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein Do Not Require Processing Prior to Binding to Class II Major Histocompatibility Complex Molecules on Living Antigen-Presenting Cells", <u>Cell. Immunol.</u>, 1995, <u>163</u>, 229-236

Jacobs et al., "Advances in Specific Therapy for Multiple Sclerosis", Neurol., 1994, <u>7</u>, 250-254

Johnson, "Experimental Therapy of Relapsing-Remitting Multiple Sclerosis with Copolymer-1", <u>Ann. Neurol.</u>, 1994, <u>36</u>(Suppl.), 115-117

Kott, et al., "COP-1 Increases Suppressor Cells Number in Multiple Sclerosis", <u>Israel Neurological Assoc.</u>, December 19-20, 1994, Herzliya (Israel), 17

EXAMINER Clumpshow

DATE CONSIDERED

04/05/03

## U.S. Department of Commerce Patent and Trademark Office

Atty. Docket No. 60726-A

Serial No. 09/885,227

OIP EINEC

(Use several sheets if necessary)

Moses Rodriguez and Daren Ure
Filing Date Group Art Unit

June 20, 2001

Applicants

Group Art Unit oc

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Mengle-Gaw, "The Major Histocompatibility Complex (MHC)", in <u>Encycl</u> Molecular Bio. (Oxford Blackwell Science Ltd, 1994) 602-606

Milo, et al., "Additive Effects of COP-1 and IFN-Beta on Immune Responses to Myelın Basic Protein", <u>Neurol.</u>, 1994, <u>44</u>(Suppl. 2), A212

Milo, et al., "Additive Effect of Copolymer-1 and Interferon-β on the Immune Response to Myelin Basic Protein", <u>Assaf Harofeh Medical Center,</u> <u>Sackler School of Medicine, Tel-Aviv University of Maryland School of Medicine</u>, 1994, 22

Milo, et al., "Copolymer-1 and Interferon-β Additively Suppress the Immune Response to Myelin Basic Protein by Inhibiting Antigen Presentation", <u>J. Neuroimmunol</u>., 1994, <u>54</u>, 183 (Abstract)

Nightingale, et al., "Access to Investigational Drugs for Treatment Purposes", Am. Family Physician, 1994, 50(4), 845-847

Schlegel, et al., "Prevention of Graft-Versus-Host Disease by Peptides Binding to Class II Major Histocompatibility Complex Molecules", <u>Blood</u>, 1994, <u>84</u>(8), 2802-2810

Stark, "Expanded Clinical Trials of Treatments for Multiple Sclerosis (MS): Copolymer 1 (COP-1) Treatment Investigational New Drug (IND) Program", Ann. Neurol., 1994, <u>36</u>, 114-115

Teitelbaum, et al., "Immunological Parameters in a Multicenter Clinical Trial of COP1 in Multiple Sclerosis (MS): A 2-year Follow-up", <u>Neurol.</u>, 1994, <u>44</u>(Suppl. 2), A358

Tisch et al., "Antigen-specific immunotherapy: Is it a Real Possibility to Combat T-Cell-Mediated autoimmunity?" <a href="Proc. Natl. Acad. Sci. U.S.A.">Proc. Natl. Acad. Sci. U.S.A.</a>, 1994, 91, 437-438

Milo, et al., "Additive Effects of Copolymer-1 and Interferon β-1b on the Immune Response to Myelin Basic Protein", <u>J. Neuroimmunol.</u>, 1995, <u>61</u>, 185-193

O'Connor, et al., "Powders" in <u>The Science and Practice of Pharmacy,</u> Remington, 1995, <u>2</u>, 1598-1614

Porter, "Coating of Pharmaceutical Dosage Forms," in <u>The Science and Practice of Pharmacy</u>, Remington, 1995, <u>2</u>, 1650-1659

Reilly, Jr., W.J., "Pharmaceutical Necessities" in <u>The Science and Practice of Pharmacy</u>, Remington, 1995, <u>2</u>, 1380-1416

Schlegel, et al., "Inhibition of Allorecognition and Prevention of Graft-vs-host Disease (GVHD) by GLAT, a Synthetic Polymer with Promiscuous Binding to Murine and Human MHC Class II Molecules", in Am. Soc. Hematology, 37<sup>th</sup> Annual Meeting, Seattle, WA (USA), December 1-5, 1995, 224a (Abstract)

EXAMINER

Muyshor

DATE CONSIDERED

04/05/03

## **U.S. Department of Commerce** Patent and Trademark Office

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Atty. Docket No. 60726-A

Serial No. 09/885,227

Applicants

Moses Rodriguez and Daren Ure

Filing Date June 20, 2001 Group Art Unit oc.

OCT 2 2 2002 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Nun, et al., "The Autoimmune Reactivity to Myelin Oligodendrocyte Glycoprotein (MOG) in Multiple Sclerosis is Potentially Pathogenic: Effect of Copolymer 1 on MOG-induced Disease", <u>J. Neurol.</u>, 1996, 243 (Suppl. 1), S14-S22

Johnson, Management of Relapsing/Remitting Multiple Sclerosis with Copolymer 1 (Copaxone)", Chemical Abstracts, 1996, 125, 291993b

Sykes, "Immunobiology of Transplantation", Faseb J., 1996, 10, 721-730

Teitelbaum, et al., "Copolymer 1 Inhibits Chronic Relapsing Experimental Allergic Encephalomyelitis Induced by Proteclipid Protein (PLP) Peptides in Mice and Interferes with PLP-specific T Cell Responses", <u>J.</u> <u>Neuroimmunol.</u>, 1996, <u>64</u>, 209-217

Aharoni, et al., "Studies on the Mechanism and Specificity of the Effect of the Synthetic Random Copolymer GLAT on Graft-versus-Host Disease", <u>Immunol. Letters</u>, 1997, <u>58</u>, 79-87

Puri et al., "Modulation of the Immune Response in Multiple Sclerosis", J. Immunol., 1997, <u>158</u>, 2471-2476

Tarcic et al., "Copolymer 1 (Copaxone) from an Idea to a Drug for Treatment of Multiple Sclerosis" Database HCAPLUS on STN, Israel: AN 1997:333270. Kim, Handasa Kim, 1997, <u>281</u>(14), 16-18 (Abstract)

Teitelbaum, et al., "Copolymer 1 from the Laboratory to FDA", Israel J. Med. Sci., 1997, 33, 280-284

Fridkis-Hareli, et al., "Promiscuous Binding of Synthetic Copolymer 1 to Purified HLA-DR Molecules", <u>J. Immunol.</u>, 1998, <u>160</u>, 4386-4397

Fridkis-Hareli, et al., "Synthetic Amino Acid Copolymers that Bind to HLA-DR Proteins and Inhibit Type II Collagen-reactive T Cell Clones", Proc. Natl. Acad. Sci., October 1998, 95, 12528-12531

Cazzato, et al., "Treatment of Multiple Sclerosis. The Present and the Study Group on Diagnosis and Therapy of Multiple Sclerosis", Database Medline on STN, Instituto do Clinica Neurologica, Universit`a, Trieste, Italy: Medline AN: 2000060325, Recent Progressi in Medicina. October 1999, <u>90</u>(10), 538-544 (Abstract)

Kepsutlu et al., "Evaluation of Chitosan Used as an Excipient in Tablet Formulations", Database HCAPLUS on STN, Department of Pharmaceutical Technology, Gulhane Military Medical Academy, Ankara, 06018, Turkcy, 1999: 590411, Acta. Pol. Pharm. 1999, <u>56</u>(3), HCAPLUS AN: (Abstract)

Prat, et al., "Lymphocyte Migration and Multiple Sclerosis: Relation with Disease Course and Therapy", Ann. Neurol., 1999, 46: 253-253

EXAMINER

Cleuyshor

DATE CONSIDERED

04/05/03

Form I	PTO-1449	U.S. Department of Comme Patent and Trademark Offi	erce	Atty. Docket No. 60726-A	Serial No. 09/885,227
p/3 4 5	32.1	N DISCLOSURE CITATION	T	Applicants Moses Rodrigue: Filing Date	<u> </u>
ί	<b>3</b>		( <del>)</del>	mne 20, 2001	1614 /642
Ž.	OTHER DO	OCUMENTS (Including Autho	or, FADEMAN	NY 16, Pertinent Pages	, Etc.)
oe	Collagen Type DR1 and DR4 Mc HCAPLUS on ST Hospital, Aarh 2000, <u>61</u> (7), 6	et al., "Synthetic II 261-273 Epitope to lecules and Collagen N, Department of Cli us, Denmark, HCAPLU 540-650 (Abstract)	Rheumat Specifical Inical I	oid Arthritis c T-cell Resp mmunology, Aa 000:455053, H	-Associated HLA onses", Database arhus University uman Immunology
oc	Durelli, "Imm Clinica delle	nunotherapeutics of Malattie del Sistema	Multipl Nervoso /	e Sclerosis" <u>Universita di</u>	, <u>Instituto d</u> <u>Torino</u> , 467-47
	<u> </u>			·	
- 1					
		/			
	141				
			<del></del> -	REC	EIVED
				OCT 2	4 2002
				TECH CENTE	ER 1600/2900
		<del></del>			
-18-				5 1011	
		<del></del>	<del></del>	<del></del>	
11111=	7				
		/			
	<del> </del>		<u> </u>		
			<del></del>		
	<del>                                     </del>				
NIMAKE	ER Muyshay	DATE CONSIDERED 04	09/03		
	MINER: Initial if citat	ion considered, whether or not	citation is i		
hrough	n citation if not in con	formance and not considered.			
pplica	.11t.				